

PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Mitchell et al.

Serial No.:

09/941,492

Examiner:

Epps-Ford, Janet L.

Filed:

January 8, 2001

Group Art Unit:

1635

For:

METHODS AND COMPOSITIONS FOR USE IN SPLICEOSOME

MEDIATED RNA TRANS-SPLICING

## **INFORMATION DISCLOSURE STATEMENT**

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Box 1450, Alexandria, VA 22313-1450.

Rochelle K. Seide

Attorney Name

Signature

32,300

PTO Registration No

12/17/2004

Date of Signature

Commissioner for Patents

Box 1450

Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §§1.97 and 1.98, applicants respectfully request that the documents listed below and on the accompanying PTO 1449 be considered by the Examiner and made of record in the above-referenced application. Copies of the documents listed are enclosed.

1. United States Patent Application Serial No. 10/693,192, filed October 23, 2003, "Screening method for identification of efficient pre-trans-splicing molecules," Mitchell *et al*.

- 2. United States Patent Application Serial No. 10/434,727, filed May 8, 2003, "Use of Spliceosome Mediated RNA Trans-Splicing To Confer Cell Selective Replication to Adenoviruses," Otto *et al*.
- 3. United States Patent Application Serial No. 10/374,784, filed February 25, 2003, "Trans-splicing mediated imaging of gene expression," Mitchell *et al*.
- 4. United States Patent Application Serial No. 10/360,787, filed June 5, 2002, "Spliceosome mediated RNA trans-splicing for correction of factor VIII genetic defects," Mitchell *et al*.
- 5. United States Patent Application Serial No. 10/198,447, filed July 17, 2002, "Spliceosome mediated RNA trans-splicing for correction of skin disorders," Mitchell *et al.*
- 6. United States Patent Application Serial No. 10/136,723, filed April 30, 2002,"Transgenic animal model for spliceosome-mediated RNA trans-splicing," Puttaraju et al.
- 7. United States Patent Application Serial No. 10/103,294, filed March 30, 2002, "Spliceosome mediated RNA trans-splicing," Mitchell *et al*.
- 8. United States Patent Application Serial No. 10/075,028, filed March 12, 2002, "Method and compositions for use in spliceosome mediated RNA trans-splicing," Mitchell *et al*.
- 9. United States Patent Application Serial No. 10/076,248, filed February 12, 2002, "Method and compositions for use in spliceosome mediated RNA trans-splicing," Mitchell *et al.*
- 10. United States Patent Application Serial No. 09/838,858, filed April 20, 2001, "Method and compositions for use in spliceosome mediated RNA trans-splicing," Mitchell et al.
- 11. United States Patent Application Serial No. 09/756,097, filed Jan. 8, 2001, "Method and compositions for use in spliceosome mediated RNA trans-splicing," Mitchell *et al*.

- 12. United States Patent Application Serial No. 09/756,095, filed Jan. 8, 2001, published August 22, 2002, as U.S. Patent Publication No. US20020115207, "Method and compositions for use on spliceosome mediated RNA trans-splicing," Mitchell *et al*.
- 13. United States Patent Application Serial No. 09/756,096, filed Jan. 8, 2001, "Methods and compositions for use in spliceosome mediated RNA trans-splicing," Mitchell *et al*.
- 14. United States Patent No. 6,280,978, filed Sept. 23, 1998, issued August 28, 2001, "Method and compositions for use in spliceosome mediated RNA trans-splicing," Mitchell *et al.*
- 15. United States Patent No. 6,083,702, filed Aug. 13, 1998, issued July 4, 2000, "Method and compositions for use in spliceosome mediated RNA trans-splicing," Mitchell *et al.*
- 16. United States Patent No. 5,998,205, filed August 1, 1997, issued December 7, 1999, "Vectors for tissue-specific replication," Hallenbeck *et al*.
- 17. United States Patent 5,962,313, filed January 16, 1997, issued October 5, 1999, "Adeno-associated virus vectors comprising a gene encoding a lyosomal enzyme," Podsakoff, et al.
- 18. United States Patent 5,962,311, filed August 21, 1996, issued October 5, 1999, "Short-shafted adenoviral fiber and its use," Wickham *et al*.
- 19. United States Patent 5,952,221, filed March 5, 1997, issued September 14, 1999, Adeno-associated virus vectors comprising a first and second nucleic acid sequence," Kurtzman et al.
- 20. United States Patent 5,932,210, filed October 28, 1997, issued August 3, 1999, "Recombinant adenoviral vector and methods of use," Gregory *et al*.

- 21. United States Patent 5,928,944, filed February 4, 1994, issued July 27, 1999, "Method of adenoviral-medicated cell transfection," Seth, et al.
- 22. United States Patent 5,922,576, filed February 27, 1998, issued July 13, 1999 "Simplified system for generating recombinant adenoviruses," He *et al*.
- 23. United States Patent 5,919,676, filed June 7, 1995, issued July 6, 1999, "Adenoviral vector system comprising Cre-loxP recombination," Graham, et al.
- 24. United States Patent 5,891,690, filed April 26, 1996, issued April 6, 1999, "Adenovirus E1-complementing cell lines," Massie.
- 25. United States Patent 5,885,808, filed July 5, 1995, issued March 23, 1999, "Adenovirus with modified binding moiety specific for the target cells," Spooner, *et al.*
- 26. United States Patent 5,877,011, filed November 20, 1996, issued March 2, 1999, "Chimeric adenoviral vectors," Armentano et al.
- 27. United States Patent 5,871,982, filed Aug. 25, 1997, issued Feb. 16, 1999, "Hybrid Adenovirus AAV Virus and Method of Use Thereof," Wilson *et al.*
- 28. United States Patent 5,869,037, filed June 26, 1996, issued February 9, 1999, "Adenoviral-mediated gene transfer to adipocytes," Crystal, *et al*.
- 29. United States Patent 5,858,351, filed January 18, 1996, issued January 12, 1999, "Methods for delivering DNA to muscle cells using recombinant adeno-associated virus vectors," Podsakoff *et al.*
- 30. United States Patent 5,851,806, filed December 14, 1995, issued December 22, 1998, "Complementary adenoviral systems and cell lines," Kovesdi, et al.

- 31. United States Patent 5,843,742, filed September 8, 1995, issued December 1, 1998, "Adeno-associated derived vector systems for gene delivery and integration into target cells," Natsoulis, *et al*.
- 32. United States Patent 5,837,484, filed January 9, 1995, issued November 17, 1998, "Stable cell lines capable of expressing the adeno-associated virus replication gene," Trempe, et al.
- 33. United States Patent 5,820,868, filed December 9, 1993, issued October 13, 1998, "Recombinant protein production in bovine adenovirus expression vector system," Mittal, *et al.*
- 34. United States Patent 5,789,390, filed July 25, 1996, issued August 4, 1998, "Method for preparing recombinant adeno-associated viruses (AAV), and uses thereof," Descamps, *et al.*
- 35. United States Patent 5,756,283, filed June 5, 1995, issued May 26, 1998, "Method for improved production of recombinant adeno-associated viruses for gene therapy," Wilson, et al.
- 36. United States Patent 5,747,072, filed April 14, 1995, issued May 5, 1998, "Adenoviral-Mediated Gene Transfer to Synovial Cells In Vivo," Davidson *et al*.
- 37. United States Patent 5,731,172, filed September 8, 1994, issued March 24, 1998, "Recombinant adenovirus and process for producing the same," Saito, *et al*.
- 38. United States Patent 5,700,470, filed March 12, 1996, issued December 23, 1997, "Recombinant adenovirus with removed EZA gene and method of preparation," Saito, et al.
- 39. United States Patent 5,670,488, filed October 13, 1993, issued September 23, 1997, "Adenovirus vector for gene therapy," Gregory, *et al*.

- 40. United States Patent 5,616,326, filed May 23, 1994, issued April 1, 1997, "Recombinant canine adenovirus 2 (CAV-2)," Spibey.
- 41. United States Patent 5,589,377, filed June 6, 1995, issued December 31, 1996, "Recombinant adeno-associated virus vectors," Lebkowski, *et al.*
- 42. United States Patent 5,585,362, filed June 7, 1993, issued December 17, 1996, "Adenovirus vectors for gene therapy," Wilson, *et al*.
- 43. United States Patent 5,354,678, filed December 21, 1992, issued October 11, 1994, "Production of recombinant adeno-associated virus vectors," Lebkowski, *et al.*
- 44. United States Patent No. 4,980,286, filed January 3, 1989, issued Dec. 25, 1990, "In vivo introduction and expression of foreign genetic material in epithelial cells," Morgan *et al.*
- 45. Bhaumik *et al.*, 2004, "Molecular Imaging of Gene Expression in Living Subjects by Splicesome-Mediated RNA Trans-Splicing," Proc. Natl. Acad. Sci. USA, 101:8693-8698.
- 46. Tahara et al., 2004, "Trans-Splicing Repair of CD40-Ligand Deficiency Results in Naturally Regulated Correction of A Mouse Model of Hyper-IgM X-Linked Immunodeficiency," Nature Medicine, 10:835-841.
- 47. Chao *et al.*, 2003, "Phenotype correction of Hemophilia A Mice by Spliceosome-Mediated RNA Trans-splicing," Nature Medicine, 9:1-5.
- 48. Liu *et al.*, 2002, "Partial Correction of Endogenous Delta 508 CFTR in Human Cystic Fibrosis Airway Epithelia by Spliceosome-Mediated RNA Trans-Splicing," Nature Biotechnology, 20:47-52.
- 49. Kim *et al.*, 2001, "Role of the Nonsense-Mediated Decay Factor hUpf3 in the Splicing Dependent Exon-Exon Junction Complex," Science 293:1832-1836.

- 50. Kirn *et al.*, 2001, "Replication-selective virotherapy for cancer:Biological principles, risk management and future directions, Nat. Med. 7:781-787.
- 51. Tian *et al.*, 2001, "Strong RNA Splicing Enhancers Identified by a Modified Method of Cycled Selection Interact with SR Protein," J. Biological Chemistry 276:33833-33839.
- 52. Mansfield *et al.*, 2000, "Repair of CFTR mRNA by splicesome-mediated RNA trans-splicing," Gene Therapy 7:1885-1895.
- 53. Tacke *et al.*, 1999, "Determinants of SR protein specificity," Curr. Opin. Cell Biol. 11:358-362.
- 54. He *et al.* 1998, "A Simplified System for Generating Recombinant Adenoviruses," Proc. Natl. Acad. Sci. USA, 95, 2509-2514.
- 55. Lan N *et al.*, 1998, "Ribozyme-mediated Repair of Sickle β-Globin mRNAs in Erythrocyte Precursors" Science 280:1593-1596.
- 56. Phylactou LA *et al.*, 1998, "Ribozyme-mediated trans-splicing of a trinucleotide repeat" Nature Genetics 18:378-381.
- 57. Staley JP *et al.*, 1998, "Mechanical Devices of the Spliceosome: Motors, Clocks, Springs and Things" Cell 92:315-326.
- 58. Bellet *et al.*, 1997, "Malignant transformation of nontrophoblastic cells is associated with the expression of chorionic gonadotropin β genes normally transcribed introphoblastic cells," Cancer Res. 57:516.
- 59. Coolidge *et al.*, 1997, "Functional analysis of the polypyrimidine tract in premRNA splicing," Nucleic Acids Res. 25:888.

- 60. Crouzet *et al.* 1997, "Recombinational Construction in Escherichia coli of Infectious Adenoviral Genomes," Proc. Natl. Acad. Sci. USA, 94, 1414-1419.
- 61. Good *et al.*, 1997, "Expression of Small, Therapeutic RNAs in Human Cell Nuclei," Gene Ther. 4:45-54.
- 62. Malek O *et al.*, 1997, "Evolution of trans-splicing plant mitochondrial introns in pre-Permian times" Proc. Nat'l. Acad. Sci. USA 94:553-558.
- 63. Chartier, *et al.* 1996, "Efficient Generation of REcombinant Adenovirus Vectors by Homologous Recombination in Escherichia coli," J Virol. 70, 4805-4810.
- 64. Hoon *et al.*, 1996, "Detection of metastatic breast cancer by β-hCG polymerase chain reaction," Int J. Cancer 69:369.
- 65. Jones JT *et al.*, 1996, "Tagging ribozyme reaction sites to follow trans-splicing in mammalian cells" Nature Medicine 2:643-648.
- 66. Krämer A, 1996, "The structure and function of proteins involved in mammalian Pre-mRNA splicing" Annu. Rev. Biochem. 65:367-404.
- 67. Miyake *et al.* 1996, "Efficient Generation of Recombinant Adenoviruses Using Adenovirus DNA-Terminal Protein Complex and A Cosmid Bearing the Full-Length Virus Genome," Proc. Natl. Acad. Sci. USA, 93, 1320-1324.
- 68. Nilsson J et al., 1996, "Multiple affinity domains for the detection, purification, and immobilization of recombinant proteins," J. Mol. Recognit., 1996, 5:585-594.
- 69. Pasman Z et al., 1996, "The 5' and 3' splice sites come together via a three dimensional diffusion mechanism" Nucleic Acids Res. 24(9):1638-1645.
  - 70. Boelens et al., "Nuclear Retention of RNA as a Mechanism," 1995 RNA 1:273-83.

- 71. Bruzik JP *et al.*, 1995, "Enhancer-dependent interaction between 5' and 3' splice sites in trans" Proc. Nat'l. Acad. Sci. USA 92:7056-7059.
- 72. Chiara MD *et al.*, 1995, "A two-step mechanism for 5' and 3' splice-site pairing" Nature 375:510-513.
- 73. Davis RE *et al.*, 1995, "RNA Trans-splicing in Flatworms" J. Biol. Chem. 270:21813-21819.
- 74. Eul J *et al.*, 1995, "Experimental evidence for RNA trans-splicing in mammalian cells: EMBO. J. 14(13):3226-3235.
- 75. Fu, 1995, "The Superfamily of Arginine/Serine-Rich Splicing Factors," RNA 1:663-680.
- 76. Bett, *et al.* 1994, "An Efficient and Flexible System for Construction if Adenovirus Vectors with Insertions or Deletions in Early Regions 1 and 3," Proc. Natl. Acad. Sci. USA, 91, 8802-6.
- 77. Hollenberg *et al.*, 1994, "Multiple promoter elements in the human chorionic gonadotropin b subunit genes distinguish their expression from luteinizing hormone  $\beta$  gene," Mol. Cell Endo., 106:111-119.
- 78. Ketner *et al.* 1994, "Efficient manipulation of the Human Adenovirus Genome as an Infectious Yeast Artificial Chromosome Clone," Proc. Natl. Acad. Sci. USA, 91, 6186-6190.
- 79. Sullenger BA *et al.*, 1994, "Ribozyme-mediated repair of defective mRNA by targeted trans-splicing" Nature 341:619-622.
  - 80. Goldspiel et al., 1993, "Human gene therapy," Clinical Pharmacy 12:488-505.

- 81. Kozarsky and Wilson, 1993, "Gene therapy:adenovirus vectors," Current Opinion in Genetics and Development 3:499-503.
- 82. Miller *et al.*, 1993, "Use of adenoviral vectors for gene transfer and expression," Meth. Enzymol. 217:581-599.
- 83. Moore and Sharp, 1993, "Evidence for two active sites in the splicesome provided by stereochemistry of pre-mRNA splicing," Nature, 365:364-368.
- 84. Moore *et al.*., 1993, "Splicing of precursors to mRNA by the spliceosome," in RNA World, R.F. Gesteland and J.F. Atkins, eds. Cold Spring Harbor Laboratory Press, 303-358.
- 85. Morgan and Anderson, 1993, "Human Gene Therapy," Ann. Rev. Biochem. 62:191-217.
  - 86. Mulligan, 1993, "The basic science of gene therapy," Science 260:926-932.
- 87. Roscigno *et al.*, 1993, "A mutational analysis of the polypyrimidine tract of introns," J. Bio. Chem., 268:11222-11229.
- 88. Tolstoshev, 1993, "Gene therapy, concepts, current trials, and future directions," Ann. Rev. Pharmacol. Toxicol. 33:573-596.
- 89. Acevedo *et al.*, 1992, "Human chorionic gonadotropin-beta subunit gene expression in cultured human fetal and cancer cells of different types and origins," Cancer 76:1467.
- 90. Bruzik JP *et al.*, 1992, "Spliced leader RNAs from lower eukaryotes are transspliced in mammalian cells," Nature 360:692-695.
- 91. Vellard M *et al.*, 1992, "A potential splicing factor is encoded by the opposite strand of the trans-spliced c-myb exon" Proc. Nat'l. Acad. Sci., 89:2511-2515.

- 92. Dingwall and Laskey, 1991, "Nuclear Targeting Sequences A Consensus?" Trends in Biochem. Sci. 16:478-481.
- 93. Ghattas *et al.*, 1991, "The Encephalomyocarditis Virus Internal Ribosome Entry Site Allows Efficient Coexpression of Two Genes from a Recombinant Provirus in Culture Cells and in Embryos," Mol. Cell Biol. 11:5848-5859.
- 94. Janknecht *et al.*, 1991, "Rapid and efficient purification of native histidine-tagged protein expressed by recombinant vaccinia virus," Proc. Natl. Acad. Sci., 88:8972-8976.
- 95. Rosenfeld *et al.* 1991, "Adenovirus-Mediated Transfer of a Recombinant α-1 Antitrypsin Gene to the Lung Epithelium in Vivo," Science. 252, 431-4.
  - 96. Wu and Wu, 1991, "Delivery systems for gene therapy," Biotherapy 3:87-95
- 97. Gilardi *et al.* 1990, "Expression of Human α<sub>1</sub>-Anti-trypsin Using a Recombinant Adenovirus Vector," FEBS Lett. 267, 60-2.
- 98. Rajkovic A *et al.*, 1990, "A spliced leader is present on a subset of mRNAs from the human parasite Schistosoma mansoni" Proc. Nat'l. Acad. Sci. USA, 87:8879-8883.
- 99. Schneider *et al.*, 1990, "Building blocks for oligonucleotide analogs with dimethyl-sulfide-sulfoxide and sulfone groups replacing phosphodiester linkages," Tet. Letters, 31:335-338.
- 100. Senapathy et al., 1990, "Splice junctions, branch point sites, and exons:sequence statistics, identification, and applications to genome project," Methods of Enzymology,

183:252-278.

101. Uhlmann et al., 1990, "Antisense Oligonucleotides: A New Therapeutic Principle," Chemical Reviews, 90:543-584.

- 102. International Patent Application No. PCT/US89/01589, published on November 2, 1989 as International Publication No. WO89/10134.
- 103. Kerem *et al.*, 1989, "Identification of the Cystic Fibrosis Gene:Genetic analysis," Science, 245:1073-1080.
- 104. Letsinger *et al.*, 1989, "Cholesterol-conjugated oligonucleotides; synthesis, properties, and activity as inhibitors of replication of human immunodeficiency virus in cell culture," Proc. Natl. Acad. Sci., 86:6553-6556
- 105. Reed, 1989, "The organization of 3' splice sites sequences in mammalian introns," Genes Dev. 3:2113.
- 106. Riordan *et al.*, 1989, "Identification of the Cystic Fibrosis Gene:Cloning and characterization of complementary DNA," Science, 245:1066-1073.
- 107. Rommens *et al.*, 1989, "Identification of the Cystic Fibrosis Gene: Chromosome walking and jumping," Science, 245:1059-1065.
- 108. Shimizu A *et al.*, 1989, "Immunoglobulin double-isotype expression by transmRNA in a human immunoglobulin transgenic mouse" Proc. Nat'l. Acad. Sci. USA 86:8020-8023.
- 109. Smith *et al.*, 1989, "Scanning from an independently specified branch point defines the 3' splice site of mammalian introns," Nature, 342:243-247.
- 110. International Patent Application No. PCT/US88/02009 of Synthetic Genetics, published on Dec. 15, 1988 as International Publication No. WO88/09810.
- 111. van der Krol *et al.*, 1988, "Modulation of eukaryotic gene expression by complementary RNA or DNA sequences," BioTechniques, 6:958-976.

- 112. Reed & Maniatis 1988, "The role of the mammalian branchpoint sequence in the pre-mRNA splicing," Genes Dev. 2:1268.
- 113. Smith *et al*, 1988, "Single-step purification of polypepetides expressed in Escherichia coli as fusions with glutathione S-transferase," Gene, 67:31
- 114. Zon *et al.*, 1988, "Oligonucleotide analogues as potential chemotherapeutic agents," Pharm. Res., 5:539-549.
- 115. Krause M *et al.*, 1987, "A Trans-spliced Leader Sequence on Actin mRNA in C. elegans" Cell 49:753-761.
- 116. Lemaitre *et al.*, 1987, "Specific antiviral activity of a poly(L-lysine)-conjugated oligodeoxyribonucleotide sequence complementary to vesicular stomatitis virus N protein mRNA initiation site," Proc. Natl. Acad. Sci., 84:648-652.
- 117. Wu and Wu, 1987, "Receptor-mediated in vitro gene transformation by a soluble DNA carrier system," J. Biol. Chem., 262:429-4432.
- 118. Dingwall and Laskey, 1986, "Protein Import into the Cell Nucleus," Ann. Rev. Cell Biol. 2:367-390.
- 119. Murphy *et al.*, 1986, "Identification of a novel Y branch structure as an intermediate in Trypanosome m RNA processing: evidence for Trans splicing," Cell, 47:517.
- 120. Smith *et al.*, 1986, "Mr 26,000 antigen of Schistosoma japonica recognized by resistant WEH1 129/J mice is a parasite glutathione S-transferase," Proc. Natl. Acad. Sci., 83:8703-8707.
- 121. Sutton RE *et al.*, 1986, "Evidence for Trans Splicing in Trypanosomes" Cell 47:527-535.

- 122. Konarska MM *et al.*, 1985, "Trans Splicing of mRNA Precursors In Vitro" Cell 46:165-171.
  - 123. Solnick D, 1985, "Trans Splicing of mRNA Precursors" Cell 42:157-164.
- 124. Talmadge *et al.*, 1984, "Only three of the seven chorionic gonadotropin beta subunit genes can be expressed in the placenta," Nucleic Acids Res. 12:8415.
- 125. Accession No. K01722, Corynebacteriophage beta diptheria toxin (DT) gene, 1983.
- 126. Berkner, *et al.* 1983, "Generation of Adenovirus by Transfection of Plasmids," Nucleic Acids Res. 11, 6003-6020.
- 127. Greenfield, 1983, "Nucleotide sequence of the structural gene for the diptheria toxin carried by corynebacteriophage β," Proc. Natl. Acad. Sci., 80:6853-6857.
- 128. Brinster *et al.*, 1982, "Regulation of metallothionein-thymidine kinase fusion plasmids injected into mouse eggs," Nature, 296:39-42.
- 129. Benoist *et al.*, 1981, "In vivo sequence requirements of the SV40 early promoter region," Nature, 290:304-310.
- 130. Wagner TE *et al.*, 1981, "Microinjection of a rabbit β-globin gene into zygotes and its subsequent expression in adult mice and their offspring" Proc. Natl. Acad. Sci. USA 78(10):6376-6380.
- 131. Yamamoto *et al.*, 1980, "Identification of a functional promoter in the long terminal repeat of Rous Sarcoma Virus," Cell, 22:39-42.
- 132. Berget SM *et al.*, 1977, "Spliced segments at the 5' terminus of adenovirus 2 late mRNA" Proc. Natl. Acad. Sci. USA 74(8):3171-3175.

- 133. Chow LT *et al.*, 1977, "An Amazing Sequence Arrangement at the 5' Ends of Adenovirus 2 Messenger RNA" Cell 12:1-8.
- 134. Graham *et al.*, 1977, "Characteristics of a Human Cell Line Transformed by DNA from Human Adenovirus Type 5," J. Gen. Virol. 36:59-72.
- 135. Uchida *et al*, 1973, "Diptheria toxin and related proteins: isolation and properties of mutant proteins related to diptheria toxin," J. Biol. Chem., 248:3838.

References #1-13 are related co-pending U.S. patent applications.

Identification of the above-listed documents is not to be construed as an admission of the applicants or attorneys for applicants that such citations are available as "prior art" against the subject application.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that the listed documents are material or constitute "prior art." If the Examiner applies the documents as prior art against any claim in the application and applicants determine that the cited documents do not constitute "prior art" under United States law, applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of the documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should the documents be applied against the claims of the present application.

This Information Disclosure Statement is being filed before the mailing date of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution, and accompanied by the fee set forth in 37 C.F.R. § 1.17(p). If any additional fee is due, or if any overpayment has been made, the Commissioner is authorized to charge any such fee or credit any overpayment, to our Deposit Account No. 02-4377. Duplicate copies of this sheet are enclosed.

Respectfully submitted,

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This Information Disclosure Statement is being filed before the mailing date of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution, and accompanied by the fee set forth in 37 C.F.R. § 1.17(p). If any additional fee is due, or if any overpayment has been made, the Commissioner is authorized to charge any such fee or credit any overpayment, to our Deposit Account No. 02-4377. Duplicate copies of this sheet are enclosed.

Respectfully submitted,

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Patent and Trademark Office

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use several sheets if necessary)

Atty. Docket No. A31304-BAE (069906.0145)	Serial No. 09/941,492
Applicant Mitchell et al.	
Filing Date Jan. 8, 2001	Group 1635
Examiner Epps-Ford, Janet L.	

			U.S. PATENT DO	CUMENTS			
*Exam. Initial.	No.	Document No.	Date	Name	Class	Subclass	Filing Date if Approximate.
	14	6,280,978	8/28/ 2001	Mitchell et al.			
	15	6,083,702	7/4/ 2000	Mitchell et al.			
	16	5,998,205	12/ 7/ 1999	Hallenbeck et al.			
	17	5,962,313	10/5/1999	Podsakoff, et al.			
	18	5,962,311	10/ 5/ 1999	Wickham et al.			
	19	5,952,221	9/14/ 1999	Kurtzman et al.			
	20	5,932,210	8/3/1999	Gregory et al.			
	21	5,928,944	7/27/ 1999	Seth, et al.			
	22	5,922,576	7/ 13/ 1999	He et al.			
	23	5,919,676	7/ 6/ 1999	Graham, et al.			···-
	24	5,891,690	4/ 6/ 1999	Massie.			
	25	5,885,808	3/ 23/ 1999	Spooner, et al.			
-	26	5,877,011	3/2/ 1999	Armentano et al.		+	
	27	5,871,982	2/ 16/ 1999	Wilson et al.			-

NY02:505504.2	
Examiner	Date Considered

<sup>\*</sup> Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 U.S. Department of Commerce (REV. 2-82) Patent and Trademark Office	Atty. Docket No. A31304-BAE (069906.0145)	Serial No. 09/941,492
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Applicant Mitchell et al.	
(Usa several sheets if necessary)	Filing Date Jan. 8, 2001	Group 1635
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	28	5,869,037	2/ 9/ 1999	Crystal, et al.			
	29	5,858,351	1/ 12/ 1999	Podsakoff et al.			
	30	5,851,806	12/ 22/ 1998	Kovesdi, et al.			
	31	5,843,742	12/ 1/ 1998	Natsoulis, et al.			
	32	5,837,484	11/ 17/ 1998	Trempe, et al.			
i=	33	5,820,868	10/ 13/ 1998	Mittal, et al.			
	34	5,789,390	8/4/1998	Descamps, et al.			
	35	5,756,283	5/26/ 1998	Wilson, et al.			·
	36	5,747,072	5/ 5/ 1998	Davidson et al.			
	37	5,731,172	3/ 24/ 1998	Saito, et al.			
	38	5,700,470	12/ 23/ 1997	Saito, et al.			
	39	5,670,488	9/ 23/ 1997	Gregory, et al.			
	40	5,616,326	4/1 1/ 1997	Spibey.			<del></del>
	41	5,589,377	12/31/1996	Lebkowski, et al.			
	_42	-5,585,362-	-12/-17/-1996	-Wilson, et-al-			
	43	5,354,678	10/ 11/ 1994	Lebkowski, et al.			:-

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Examiner

Date Considered

<sup>\*</sup> Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 U.S. Department of Commerce (REV. 2-82) Patent and Trademark Office	Atty. Docket No. A31304-BAE (069906.0145)	Serial No. 09/941,492
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Applicant Mitchell et al.	
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			U.S. I	PATENT DO	CUMENTS			,
*Exam. Initial	No.	Document No.		Date	Name	Class	Subclass	Filing Date if Approximate.
	44	4,980,286	,	12/. 25/ 1990	Morgan et al.			
					- 1185			

		FORE	IGN PATENT DO	CUMENTS				
Exam Initial	No.	Document No.	Date	Country	Class	Subclass	Translation	on No
	102	WO8910134	11/02/89	WIPO				
	110	WO8809810	12/15/88	WIPO			•	

Exam Initial	No.	OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, Etc.)
	1	United States Patent Application Serial No. 10/693,192, filed October 23, 2003, "Screening method for identification of efficient pre-trans-splicing molecules," Mitchell et al.
	2	United States Patent Application Serial No. 10/434,727, filed May 8, 2003, "Use of spliceosome mediated RNA trans-splicing to confer cell selective replication to adenoviruses," Otto et al.
	3	United States Patent Application Serial No. 10/374,784, filed February 25, 2003, "Trans-splicing mediated imaging of gene expression," Mitchell et al.
	4	 United States Patent Application Serial No. 10/360,787, filed June 5, 2002, "Spliceosome mediated RNA trans-splicing-for correction of factor-VIII genetic defects," Mitchell et al.

NY02:505504.2		
Examiner	Date Considered	,

<sup>\*</sup> Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

BY APPLICANT  Mitchell et al.  Filing Date Jan. 8, 2001  Filing Date Jan. 8, 2001	Form PTO-1449 U.S. Department of Commerce (REV. 2-82) Patent and Trademark Office	Atty. Docket No. A31304-BAE (069906.0145)	Serial No. 09/941,492
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Exam Initial	No.	OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, Etc.)
	5	United States Patent Application Serial No. 10/198,447, filed July 17, 2002, "Spliceosome mediated RNA transsplicing for correction of skin disorders," Mitchell et al.
	6	United States Patent Application Serial No. 10/136,723, filed April 30, 2002, "Transgenic animal model for spliceosome-mediated RNA trans-splicing," Puttaraju et al.
	7	United States Patent Application Serial No. 10/103,294, filed March 30, 2002, "Spliceosome mediated RNA trans-splicing," Mitchell et al.
	8	United States Patent Application Serial No. 10/075,028, filed March 12, 2002, "Method and compositions for use in spliceosome mediated RNA trans-splicing," Mitchell et al.
	9	United States Patent Application Serial No. 10/076,248, filed February 12, 2002, "Method and compositions for use in spliceosome mediated RNA trans-splicing," Mitchell et al.
	10	United States Patent Application Serial No. 09/838,858, filed April 20, 2001, "Method and compositions for use in spliceosome mediated RNA trans-splicing," Mitchell et al.
	11	United States Patent Application Serial No. 09/756,097, filed Jan. 8, 2001, "Method and compositions for use in spliceosome mediated RNA trans-splicing," Mitchell et al.
	12	United States Patent Application Serial No. 09/756,095, filed Jan. 8, 2001, published August 22, 2002, as U.S. Patent Publication No. US20020115207, "Method and compositions for use on spliceosome mediated RNA transsplicing," Mitchell et al.
	13	United States Patent Application Serial No. 09/756,096, filed Jan. 8, 2001, "Methods and compositions for use in spliceosome mediated RNA trans-splicing," Mitchell et al.
	45	Bhaumik et al., 2004, "Molecular Imaging of Gene Expression in Living Subjects by Splicesome-Mediated RNA Trans-Splicing," Proc. Natl. Acad. Sci. USA, 101:8693-8698.

NY02:505504.2	
Examiner	Date Considered

<sup>\*</sup> Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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(Use several sheets if necessary)	Filing Date Jan. 8, 2001	Group 1635
DEC 2 3 7504 E	Examiner Epps-Ford, Janet L.	
REAT & TO ADEMINE		

Exam Initial	No.	OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, Etc.)
	46	Tahara et al., 2004, "Trans-Splicing Repair of CD40-Ligand Deficiency Results in Naturally Regulated Correction of A Mouse Model of Hyper-IgM X-Linked Immunodeficiency," Nature Medicine, 10:835-841.
	47	Chao et al., 2003, "Phenotype correction of Hemophilia A Mice by Spliceosome-Mediated RNA Trans-splicing," Nature Medicine, 9:1-5.
·	48	Liu et al., 2002, "Partial Correction of Endogenous Delta 508 CFTR in Human Cystic Fibrosis Airway Epithelia by Spliceosome-Mediated RNA Trans-Splicing," Nature Biotechnology, 20:47-52.
	49	Kim et al., 2001, "Role of the Nonsense-Mediated Decay Factor hUpf3 in the Splicing Dependent Exon-Exon Junction Complex," Science 293:1832-1836.
	50	Kirn et al., 2001, "Replication-selective virotherapy for cancer:Biological principles, risk management and future directions, Nat. Med. 7:781-787.
	51	Tian et al., 2001, "Strong RNA Splicing Enhancers Identified by a Modified Method of Cycled Selection Interact with SR Protein," J. Biological Chemistry 276:33833-33839.
	52	Mansfield et al., 2000, "Repair of CFTR mRNA by splicesome-mediated RNA trans-splicing," Gene Therapy 7:1885-1895.
	53	Tacke et al., 1999, "Determinants of SR protein specificity," Curr. Opin. Cell Biol. 11:358-362.
	54	He et al. 1998, "A Simplified System for Generating Recombinant Adenoviruses," Proc. Natl. Acad. Sci. USA, 95, 2509-2514.
	55	Lan N et al., 1998, "Ribozyme-mediated Repair of Sickle β-Globin mRNAs in Erythrocyte Precursors" Science 280:1593-1596.
	56	Phylactou LA et al., 1998, "Ribozyme-mediated trans-splicing of a trinucleotide repeat" Nature Genetics 18:378-381.

NY02:505504.2		 
Examiner	Date Considered	

<sup>\*</sup> Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Janet L.
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Exam Initial	No.	OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, Etc.)
	57	Staley JP et al., 1998, "Mechanical Devices of the Spliceosome: Motors, Clocks, Springs and Things" Cell 92:315-326.
	58	Bellet et al., 1997, "Malignant transformation of nontrophoblastic cells is associated with the expression of chorionic gonadotropin β genes normally transcribed introphoblastic cells," Cancer Res. 57:516.
	59	Coolidge et al., 1997, "Functional analysis of the polypyrimidine tract in pre-mRNA splicing," Nucleic Acids Res. 25:888.
	60	Crouzet et al. 1997, "Recombinational Construction in Escherichia coli of Infectious Adenoviral Genomes," Proc. Natl. Acad. Sci. USA, 94, 1414-1419.
	61	Good et al., 1997, "Expression of Small, Therapeutic RNAs in Human Cell Nuclei," Gene Ther. 4:45-54.
	62	Malek O et al., 1997, "Evolution of trans-splicing plant mitochondrial introns in pre-Permian times" Proc. Nat'l. Acad. Sci. USA 94:553-558.
	63	Chartier, et al. 1996, "Efficient Generation of REcombinant Adenovirus Vectors by Homologous Recombination in Escherichia coli," J Virol. 70, 4805-4810.
	64	Hoon et al., 1996, "Detection of metastatic breast cancer by β-hCG polymerase chain reaction," Int J. Cancer 69:369.
	65	Jones JT et al., 1996, "Tagging ribozyme reaction sites to follow trans-splicing in mammalian cells" Nature Medicine 2:643-648.
	66	Krämer A, 1996, "The structure and function of proteins involved in mammalian Pre-mRNA splicing" Annu. Rev. Biochem. 65:367-404.
	67	Miyake et al. 1996, "Efficient Generation of Recombinant Adenoviruses Using Adenovirus DNA-Terminal Protein Complex and A Cosmid Bearing the Full-Length Virus Genome," Proc. Natl. Acad. Sci. USA, 93, 1320-1324.
	68	Nilsson J et al., 1996, "Multiple affinity domains for the detection, purification, and immobilization of recombinant proteins," J. Mol. Recognit., 1996, 5:585-594.
NY02:50	5504.2	
Examine	er	Date Considered

<sup>\*</sup> Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 U.S. Department of Commerce (REV. 2-82) Patent and Trademark Office	Atty. Docket No. A31304-BAE (069906.0145)	Serial No. 09/941,492
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Applicant Mitchell et al.	
Use several sheets if necessary)	Filing Date Jan. 8, 2001	Group 1635
DEC 2 3 2304 2	Examiner Epps-Ford, Janet L.	
TRADEMENTS		

Exam Initial	No.	OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, Etc.)
	69	Pasman Z et al., 1996, "The 5' and 3' splice sites come together via a three dimensional diffusion mechanism" Nucleic Acids Res. 24(9):1638-1645.
	70	Boelens et al., "Nuclear Retention of RNA as a Mechanism," 1995 RNA 1:273-83.
	71	Bruzik JP et al., 1995, "Enhancer-dependent interaction between 5' and 3' splice sites in trans" Proc. Nat'l. Acad. Sci. USA 92:7056-7059.
	72	Chiara MD et al., 1995, "A two-step mechanism for 5' and 3' splice-site pairing" Nature 375:510-513.
	73	Davis RE et al., 1995, "RNA Trans-splicing in Flatworms" J. Biol. Chem. 270:21813-21819.
	74	Eul J et al., 1995, "Experimental evidence for RNA trans-splicing in mammalian cells: EMBO. J. 14(13):3226-3235.
	75	Fu, 1995, "The Superfamily of Arginine/Serine-Rich Splicing Factors," RNA 1:663-680.
	76	Bett et al. 1994, "An Efficient and Flexible System for Construction if Adenovirus Vectors with Insertions or Deletions in Early Regions 1 and 3," Proc. Natl. Acad. Sci. USA, 91,8802-6.
	77	Hollenberg et al., 1994, "Multiple promoter elements in the human chorionic gonadotropin b subunit genes distinguish their expression from luteinizing hormone β gene," Mol. Cell Endo., 106:111-119.
	78	Ketner et al. 1994, "Efficient manipulation of the Human Adenovirus Genome as an Infectious Yeast Artificial Chromosome Clone," Proc. Natl. Acad. Sci. USA, 91, 6186-6190.
	79	Sullenger BA et al., 1994, "Ribozyme-mediated repair of defective mRNA by targeted trans-splicing" Nature 341:619-622.
	80	Goldspiel et al., 1993, "Human gene therapy," Clinical Pharmacy 12:488-505.
	81	Kozarsky and Wilson, 1993, "Gene therapy:adenovirus vectors," Current Opinion in Genetics and Development 3:499-503.
	82	Miller et al., 1993, "Use of adenoviral vectors for gene transfer and expression," Meth. Enzymol. 217:581-599.

NY02:505504.2	
Examiner	Date Considered

<sup>\*</sup> Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 U.S. Department of Commerce (REV. 2-82) Patent and Trademark Office	Atty. Docket No. A31304-BAE (069906.0145)	Serial No. 09/941,492
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DEC 2 3 2004	Examiner Epps-Ford, Janet L.	
THAT & THADEWARE		

Exam Initial	No.	OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, Etc.)
	83	Moore and Sharp, 1993, "Evidence for two active sites in the splicesome provided by stereochemistry of premRNA splicing," Nature, 365:364-368.
	84	Moore et al, 1993, "Splicing of precursors to mRNA by the spliceosome," in RNA World, R.F. Gesteland and J.F. Atkins, eds. Cold Spring Harbor Laboratory Press, 303-358.
•	85	Morgan and Anderson, 1993, "Human Gene Therapy," Ann. Rev. Biochem. 62:191-217.
	86	Mulligan, 1993, "The basic science of gene therapy," Science 260:926-932.
	87	Roscigno et al., 1993, "A mutational analysis of the polypyrimidine tract of introns," J. Bio. Chem., 268:11222-11229.
	88	Tolstoshev, 1993, "Gene therapy, concepts, current trials, and future directions," Ann. Rev. Pharmacol. Toxicol. 33:573-596.
	89	Acevedo et al., 1992, "Human chorionic gonadotropin-beta subunit gene expression in cultured human fetal and cancer cells of different types and origins," Cancer 76:1467.
	90	Bruzik JP et al., 1992, "Spliced leader RNAs from lower eukaryotes are trans-spliced in mammalian cells," Nature 360:692-695.
	91	Vellard M et al., 1992, "A potential splicing factor is encoded by the opposite strand of the trans-spliced c-myb exon" Proc. Nat'l. Acad. Sci., 89:2511-2515.
	92	Dingwall and Laskey, 1991, "Nuclear Targeting Sequences - A Consensus?" Trends in Biochem. Sci. 16:478-481.
	93	Ghattas et al., 1991, "The Encephalomyocarditis Virus Internal Ribosome Entry Site Allows Efficient Coexpression of Two Genes from a Recombinant Provirus in Culture Cells and in Embryos," Mol. Cell Biol. 11:5848-5859.
	94	Janknecht et al., 1991, "Rapid and efficient purification of native histidine-tagged protein expressed by recombinant vaccinia virus," Proc. Natl. Acad. Sci., 88:8972-8976.
	95_	Rosenfeld et-al.—1991,—"Adenovirus-Mediated—Transfer-of-a-Recombinant-α-1-Antitrypsin-Gene-to-the-Lung- Epithelium in Vivo," Science. 252, 431-4.

NY02:505504.2		
Examiner	Date Considered	

<sup>\*</sup> Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Use several sheets if necessary)	Filing Date Jan. 8, 2001	Group 1635
DEC 2 3 2004 E	Examiner Epps-Ford, Janet L.	
TRADEMARK		

Exam Initial	No.	OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, Etc.)
	96	Wu and Wu, 1991, "Delivery systems for gene therapy," Biotherapy 3:87-95.
	97	Gilardi et al. 1990, "Expression of Human α <sub>1</sub> -Anti-trypsin Using a Recombinant Adenovirus Vector," FEBS Lett. 267, 60-2.
	98	Rajkovic A et al., 1990, "A spliced leader is present on a subset of mRNAs from the human parasite Schistosoma mansoni" Proc. Nat'l. Acad. Sci. USA, 87:8879-8883.
	99	Schneider et al., 1990, "Building blocks for oligonucleotide analogs with dimethyl-sulfide-sulfoxide and sulfone groups replacing phosphodiester linkages," Tet. Letters, 31:335-338.
	100	Senapathy et al., 1990, "Splice junctions, branch point sites, and exons:sequence statistics, identification, and applications to genome project," Methods of Enzymology, 183:252-278.
	101	Uhlmann et al., 1990, "Antisense Oligonucleotides: A New Therapeutic Principle," Chemical Reviews, 90:543-584.
	103	Kerem et al., 1989, "Identification of the Cystic Fibrosis Gene:Genetic analysis," Science, 245:1073-1080.
	104	Letsinger et al., 1989, "Cholesterol-conjugated oligonucleotides; synthesis, properties, and activity as inhibitors of replication of human immunodeficiency virus in cell culture, " Proc. Natl. Acad. Sci., 86:6553-6556.
	105	Reed, 1989, "The organization of 3' splice sites sequences in mammalian introns," Genes Dev. 3:2113.
	106	Riordan et al., 1989, "Identification of the Cystic Fibrosis Gene:Cloning and characterization of complementary DNA," Science, 245:1066-1073.
	107	Rommens et al., 1989, "Identification of the Cystic Fibrosis Gene: Chromosome walking and jumping," Science, 245:1059-1065.
	108	Shimizu A et al., 1989, "Immunoglobulin double-isotype expression by trans-mRNA in a human immunoglobulin transgenic mouse" Proc. Nat'l. Acad. Sci. USA 86:8020-8023.
	109	Smith et al., 1989, "Scanning from an independently specified branch point defines the 3' splice site of mammalian-introns," Nature, 342:243-247.
	111	van der Krol et al., 1988, "Modulation of eukaryotic gene expression by complementary RNA or DNA sequences," BioTechniques, 6:958-976.
NY02:505	5504.2	
Examine	r	Date Considered

<sup>\*</sup> Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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DEC 2 3 ZEON E	Examiner Epps-Ford, Janet L.	
TATA TRADE		

Exam Initial	No.	OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, Etc.)
	112	Reed & Maniatis 1988, "The role of the mammalian branchpoint sequence in the pre-mRNA splicing," Genes Dev. 2:1268.
	113	Smith et al, 1988, "Single-step purification of polypepetides expressed in Escherichia coli as fusions with glutathione S-transferase," Gene, 67:31.
	114	Zon et al., 1988, "Oligonucleotide analogues as potential chemotherapeutic agents," Pharm. Res., 5:539-549.
	115	Krause M et al., 1987, "A Trans-spliced Leader Sequence on Actin mRNA in C. elegans" Cell 49:753-761.
	116	Lemaitre et al., 1987, "Specific antiviral activity of a poly(L-lysine)-conjugated oligodeoxyribonucleotide sequence complementary to vesicular stomatitis virus N protein mRNA initiation site," Proc. Natl. Acad. Sci., 84:648-652.
	117	Wu and Wu, 1987, "Receptor-mediated in vitro gene transformation by a soluble DNA carrier system," J. Biol. Chem., 262:429-4432.
	118	Dingwall and Laskey, 1986, "Protein Import into the Cell Nucleus," Ann. Rev. Cell Biol. 2:367-390.
	119	Murphy et al., 1986, "Identification of a novel Y branch structure as an intermediate in Trypanosome m RNA processing: evidence for Trans splicing," Cell, 47:517.
	120	Smith et al., 1986, "Mr 26,000 antigen of Schistosoma japonica recognized by resistant WEH1 129/J mice is a parasite glutathione S-transferase," Proc. Natl. Acad. Sci., 83:8703-8707.
	121	Sutton RE et al., 1986, "Evidence for Trans Splicing in Trypanosomes" Cell 47:527-535.
	122	Konarska MM et al., 1985, "Trans Splicing of mRNA Precursors In Vitro" Cell 46:165-171.
	123	Solnick D, 1985, "Trans Splicing of mRNA Precursors" Cell 42:157-164.
	124	Talmadge et al., 1984, "Only three of the seven chorionic gonadotropin beta subunit genes can be expressed in the placenta," Nucleic Acids Res. 12:8415.
	125	Accession No. K01722, Corynebacteriophage beta diptheria toxin (DT) gene, 1983.

NY02:505504.2		
Examiner	Date Considered	,

<sup>\*</sup> Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 U.S. Department of Commerce (REV. 2-82) Patent and Trademark Office	Atty. Docket No. A31304-BAE (069906.0145)	Serial No. 09/941,492	
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Use several sheets if necessary)	Filing Date Jan. 8, 2001	Group 1635	
DEC 5 3 5004 E	Examiner Epps-Ford, Janet L.		
BITAT & TRADEMINE			

Exam Initial	No.	OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, Etc.)		
	126	Berkner, et al. 1983, "Generation of Adenovirus by Transfection of Plasmids," Nucleic Acids Res. 11, 6003-6020.		
	127	Greenfield, 1983, "Nucleotide sequence of the structural gene for the diptheria toxin carried by corynebacteriophage β," Proc. Natl. Acad. Sci., 80:6853-6857.		
	128	Brinster et al., 1982, "Regulation of metallothionein-thymidine kinase fusion plasmids injected into mouse eggs," Nature, 296:39-42.		
	129	Benoist et al., 1981, ""In vivo sequence requirements of the SV40 early promoter region," Nature, 290:304-310.		
	130	Wagner TE et al., 1981, "Microinjection of a rabbit β-globin gene into zygotes and its subsequent expression in adult mice and their offspring" Proc. Natl. Acad. Sci. USA 78(10):6376-6380.		
	131	Yamamoto et al., 1980, "Identification of a functional promoter in the long terminal repeat of Rous Sarcoma Virus," Cell, 22:39-42.		
	132	Berget SM et al., 1977, "Spliced segments at the 5' terminus of adenovirus 2 late mRNA" Proc. Natl. Acad. Sci. USA 74(8):3171-3175.		
	133	Chow LT et al., 1977, "An Amazing Sequence Arrangement at the 5' Ends of Adenovirus 2 Messenger RNA" Cell 12:1-8.		
	134	Graham et al., 1977, "Characteristics of a Human Cell Line Transformed by DNA from Human Adenovirus Type 5," J. Gen. Virol. 36:59-72.		
	135	Uchida et al, 1973, "Diptheria toxin and related proteins: isolation and properties of mutant proteins related to diptheria toxin," J. Biol. Chem., 248:3838.		

NY02:505504.2	The state of the s	
Examiner	Date Considered	

<sup>\*</sup> Examiner: Initial citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.